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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/185,243 | 11/03/1998 | TOM TSANG | 15907-0016 | 5192 |

22850 7590 11/04/2002

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Re: AFT

Office Action Summary

Application No.

09/185,243

Applicant(s)

TSANG ET AL.

Examiner

Scott Priebe

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5.9-18.20-26.33.35-39 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.5.9-18.20-26.33.35-39 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1632.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/02 has been entered. Claims 6, 7, and 41 have been cancelled. Claims 1, 9, 18, 33, 38 and 39 have been amended. Claim 47 has been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed 7/2/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original

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disclosure is as follows: amended Table 4. Table 4 has been amended to alter several of the numerical values originally disclosed. Applicant asserts that the amendment corrects mistakes Table 4 in the original application, but has provided no evidence that the original filed Table 4 was in error, e.g. a declaration filed under 37 CFR 1.132 to show evidence for the basis of the error, how it was made, when it was discovered, evidence that the corrected values were known to applicant at the time the application was filed, etc. Applicant also asserts that the changes are supported by the original specification, but has failed to indicate where such support is to be found. It is Applicant's burden to identify such support to the examiner. See MPEP 714.02 and 2163.06, section I).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 9 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 has been amended to delete reference to tat as being the transactivating factor, consequently, the claim embraces any transactivating factor able to activate transcription from HIV-1 or HIV-2 promoters. Conversely, new claim 47 recites tat as the transactivating factor without limitation of the second promoter which it activates to HIV-1 or HIV-2 promoters. This

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broadening of the claimed embodiments of the invention where the transactivator is tat or where the second promoter is the HIV-1 or HIV-2 promoter is not clearly supported in the original specification. The original specification describes embodiments wherein the transactivator is tat when the second promoter is the HIV-1 or HIV-2 promoter (page 32, pages 34-35, original claims 9 and 43). The original specification does not mention a promoter other than the HIV-1 and HIV-2 promoters that it would transactivate, nor does it disclose any transactivator other than tat which would transactivate the HIV-1 or HIV-2 promoter. There is no evidence of record indicating that applicant had contemplated any second promoter other than the HIV promoters when tat is the transactivator, nor any transactivator other than tat when the second promoter is the HIV-1 or HIV-2 promoter. It is suggested that claim 47 be cancelled, and claim 9 be amended to recite its original limitations.

Claims 1, 5, 9-15, 17, 18, 20-26, 33, and 35-38 remain rejected and claim 47 is rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 6/26/00 because the specification, while being enabling for methods of using the recited expression construct to effect expression of a selected polynucleotide in a mammalian cell *in vitro*, wherein the construct comprises a HSP25, HSP27, HSP60, HSP70, HSP90 or ubiquitin heat shock promoter operably linked to a gene encoding a transactivating factor, and a second promoter, activated by the transcription factor, operably linked to a selected polynucleotide, does not reasonably provide enablement for any other method of using the expression construct. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In the Office action of 3/28/01, claims 1, 5-7, 9, 18, 20-26, 33 and 35-38 had been rejected. It is unclear why the rejection of claims 10-15 and 17 was dropped. None of the arguments provided in the amendment of 12/28/00 were directed to claims 10-15 and 17 specifically, and the examiner did not give reasons for withdrawing the rejection of claims 10-15 and 17. It is unclear whether it was intentional or if it was a typographical error; "9, 18" vs. "9-18". In any event, withdrawal of the rejection of claims 10-15 and 17 was premature, and the rejection of these claims is hereby re-instated for the original reasons of record.

Applicant's arguments filed 7/2/01 have been fully considered but they are not persuasive. Applicant indicates that the base claims have been amended to limit the heat shock promoter to HSP25, HSP27, HSP60, HSP70, HSP90 or ubiquitin heat shock promoter, and suggests that the rejection be withdrawn. However, the scope of the heat shock promoter was only one issue raised in the rejection (see Office action of 6/26/00 at pages 5-14, except for the 2nd full para. of page 13). The amendment does not address these other issues, nor have any arguments traversing the other grounds of rejection been presented.

Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 20 recites the limitation "said first and second expression constructs" in line 1. Claims 21 and 22 recite the limitation "said expression constructs" in line 1. There is insufficient antecedent basis for these limitations in the claims. Claim 18 recites only a single expression construct.

Claim Rejections - 35 USC § 102

Claims 1, 5, 10-12, 14, 16, 39, 43, 44, and 46 remain rejected and claims 9 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bromley et al. (EP 0299127) for the reasons of record set forth in the Office action of 6/26/00.

The rejection of claim 9 is re-instated. It is unclear whether omission of claim 9 from the rejection in the Office action of 3/28/01 was inadvertent or deliberate, particularly since the rejection of claim 43, directed to the same limitations, was not withdrawn. The action of 3/28/01 gives no reason for the withdrawal of the rejection of claim 9 and the response of 12/28/00 does not argue claim 9 specifically. In any event, withdrawal of the rejection of claim 9 was premature.

Claim Rejections - 35 USC § 103

Claims 1, 10, 12, 13, 15, 16, 39, and 44-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gage et al. (US 5,770,414) in view of Bromley et al. (EP 0299127) for the reasons of record set forth in the Office action of 3/28/01. The order of references has been

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reversed to accurately reflect the rejection as originally written as modifying Gage by the teachings of Bromley.

Claims 1 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley et al. (EP 0299127), taken with any one of Stover (US 5,583,038), Hickey et al. (Nucleic Acids Res. 14: 4127-4145, 1986), Gaestel et al. (Gene 128: 279-283, 1993), Dale (Gene 172: 279-284, 1996), or Quail et al. (EP 0342926) for the reasons of record set forth in the Office action of 6/26/00.

Claims 1, 10, 11, 39, and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley et al. (EP 0299127), taken with any one of Dubensky, Jr. et al. (US 5,814,482), Scott et al. (WO 95/09913), Saito et al. (US 5,817,492), Weinberg et al. (WO 89/10412), Beach et al. (US 5,889,169) or Tewari et al. (Biochim. Biophys. Acta 1209: 293-295, 1994) for the reasons of record set forth in the Office action of 6/26/00.

Claims 1, 9, 39, and 43 are again rejected and claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley et al. (EP 0299127), taken with Emerman et al. (EMBO J. 6: 3755-3760, 1987) for the reasons of record set forth in the Office action of 6/26/00.

The rejection of claims 1, 9, 39, and 43 is re-instated. It is unclear whether withdrawal of this rejection in the Office action of 3/28/01 was inadvertent or deliberate. The action of 3/28/01

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gives no reason for the withdrawal of this rejection, and the response of 12/28/00 did not respond to this rejection. In any event, withdrawal of the rejection was premature.

Claims 1 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley et al. (EP 0299127), taken with any one of Loeb et al. (US 5,877,010), Hancock (In Methods in Molecular Biology, 8, Practical Virology, Viral Vectors for Gene Expression, ed. M. Collins, Humana Press Inc. Clifton, New Jersey, 1991, Chapter 14) , or Talavera (In Methods in Molecular Biology, 8, Practical Virology, Viral Vectors for Gene Expression, ed. M. Collins, Humana Press Inc. Clifton, New Jersey, 1991, Chapter 21, pages 235-248) for the reasons of record set forth in the Office action of 6/26/00.

Response to Arguments

Applicant's arguments filed 7/2/01 have been fully considered but they are not persuasive for the reasons of record set forth in the Office action of 7/10/01. In addition, Applicant continues to take issue with Bromley in not providing explicit teachings on how to construct a single vector or construct which contains the two hybrid genes, instead of on two vectors as exemplified. No evidence of record has been presented showing that Bromley would have needed to provide such teachings to one of ordinary skill in the pertinent art; who are scientists with doctoral degrees and research experience. This argument is absurd on its face. For example, see Gage which teaches such constructs, e.g. Fig. 1. The prior art is replete with examples of vectors

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comprising multiple transcription units or expression cassettes. Consider for example plasmid expression vectors comprising a reporter or marker gene and a gene of interest, each operably linked to their own promoter, e.g. Bromley at pages 5-6, section 1.4; Loeb, Fig. 1; Stover, Figs. 1-4. Furthermore, the instant specification does not disclose any problems with constructing vectors with multiple transgenes, or any particular problems with inclusion of genes under control of HSP promoters, nor does it disclose any methodology for vector construction that was not already known in the art.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER